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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Victor S. Polyakov

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EXAMINER

SOROUGH, ALI

ART UNIT

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1616

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,961	Applicant(s) POLYAKOV ET AL.	
	Examiner ALI SOROUGH	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-20, 22, 25, 26, 37, 41 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-20, 22, 25, 26, 37, 41 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 26, 37, 41, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 25, 26, 37, 41, and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating an infection, dandruff, acne, and/or dermatitis, does not reasonably provide enablement for the prevention of infection, dandruff, acne, and/or dermatitis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the

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art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The Nature of the Invention

The rejected claims 25, 26, 37, 41, and 46 are drawn to a method for treating or preventing infection, dandruff, acne, and/or dermatitis comprising administering to a subject a pharmaceutical composition comprising: an ionogenic surfactant, a metal chelating complex, a solvent, and a pharmaceutical acceptable carrier.

The state of the prior art

The state of the art regarding preventing an infection, dandruff, acne and/or dermatitis is relatively high. The skilled artisan would view that the prevention of an infection, dandruff, acne, and/or dermatitis as highly unlikely. For example, one of ordinary skill in the art would know that attempts at preventing an infection with HIV, picornaviruses, or coronaviruses have not been successful. Further, attempts at preventing of acne or dandruff have not been successful either.

The relative skill of those in the art

The relative skill of those in the art is high.

The breadth of the claims

Claims 25, 26, 37, 41, and 46 embraces a method for treating or preventing infection, dandruff, acne, and/or dermatitis which is very broad.

The amount of guidance or direction presented

In the instant case, working examples are presented for treating infections caused by specific viruses, bacteria, and fungi; however, there is a lack of working examples presented in the specification as filed showing how to prevent an infection, dandruff, acne, and/or dermatitis. Note that lack of a working example is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP § 2164.

The presence or absence of working examples

Applicant provides working examples for treating infections caused by specific viruses, bacteria, and fungi. However, applicant does not provide any working examples for preventing an infection, dandruff, acne, and/or dermatitis.

The quantitation of experimentation necessary

Claims 25, 26, 37, 41, and 46 read on a method for treating or preventing infection, dandruff, acne, and/or dermatitis which is very broad. As discussed above, the specification provides examples for treating infections caused by specific viruses, bacteria, and fungi, but the specification fails to provide sufficient support for preventing

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an infection, dandruff, acne, and/or dermatitis. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

In view of the breadth of the claims, unpredictability of preventing an infection, dandruff, acne, and/or dermatitis, and the lack of working examples regarding the activity as claimed, one skilled in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-4, 7, 10-20, 22, 25, 26, 37, 41, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mottahedeh (Canadian Patent Application 2245254, Published 03/02/2000) in view of Brinkman et al. (US Patent 4089945, Published 05/16/1978).

Applicant Claims

Applicant claims a pharmaceutical composition comprising: an ionogenic surfactant, a metal chelating complex, a solvent, and a pharmaceutically acceptable carrier. Applicant further claims a method of treating or preventing infection, dandruff, acne, and or dermatitis.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Mottahedeh teaches, "A method is provided to treat and/ or prevent microbially induced as well as chronically endogenous skin diseases such as seborrheic dermatitis, eczema or psoriasis, by topical application to the skin and washing in a shampoo containing an effective amount of a treatment composition containing an alkyl polyglycosides and iodine in a pharmaceutically acceptable vehicle." (See abstract). "It is therefore an object of the present invention to provide an effective treatment for inflammatory dermatoses, seborrheic dermatitis, eczema and psoriasis; and resultant dandruff, itching sequelae or scaling." (See page 4, Lines 2-4). The composition comprises : "5-85% amount by weight of a pharmaceutical carrier; 10-30% amount by weight of shampoo components; 0.3-5% amount by weight of a bactericide; 0.5-5% amount by weight of an alkyl polyglycoside; ..." (See page 8, claim 1). Mottahedeh

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further teaches that the pharmaceutical carrier is a solvent, diluents, carrier, or any mixture thereof, wherein the carrier can be water and the solvent can be isopropanol. (See page 8, claim 2). Mottahedeh teaches the composition can comprise bactericide or anti-fungal agent, anti-oxidants, vitamins, minerals, botanical or animal extracts. (See page 7, Lines 5-15).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Mottahedeh lacks a teaching wherein the composition comprises an ionogenic surfactant and a metal chelating complex. This deficiency is cured by the teachings of Brinkman et al.

Brinkman et al teach “An antidandruff shampoo comprising a surfactant, sulfur or selenium sulfide and a metallic complex wherein the cation of said complex is an ion of a heavy metal and the complexing agent is selected so that the complex can effectively counteract the formation of sulfide off odors.” (See abstract). “The surfactant component comprises from about 10% to about 50% by weight of the composition, preferably 10% to about 20%. Any nonsoap surfactant is suitable for use including anionic, nonionic, amphoteric and zwitterionic types. Cationic surfactants may also be used ...” (See column 2, Lines 32-37). A specific example of a cationic surfactant that may be used with the invention of Brinkman et al. is cetylpyridinium chloride. (See column 5, Lines 33-39). “Metallic cation complexes generally comprise from about 0.1% to about 2% by weight of the compositions herein, preferably from about 0.2% to about

0.75% by weight." (See column 6, Lines 22-25). "A most preferred complex is the copper complex of ethylenediaminetetraacetic acid." (See column 6, Lines 60-62). "The shampoos herein are preferably in the form of liquids or creams in which water is the principal diluent. The level of water in the compositions is typically from about 35% to about 89% by weight." (See column 6, Lines 65-68).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Mottahedeh with Brinkman et al. One would have been motivated to do so because Mottahedeh teaches that the composition comprises shampoo components and that the composition is useful in treating dandruff with a bactericide. Brinkman et al. teaches an antidandruff shampoo and therefore one would have expected success in combining the compositions of Mottahedeh and Brinkman et al. It would have also been obvious to use Zn-EDTA as the metal chelating agent because Brinkman et al. teaches a metallic cation complex agent being a complex of metallic ion with complexing agent such as EDTA. Therefore, it would have been obvious to use Zn-EDTA instead of the preferred complex of Cu-EDTA taught by Brinkman et al. With regard to the instant concentrations (claims 15-17), it would have been obvious to one of ordinary skill in the art to arrive at the instant concentrations through routine optimization. For the foregoing reasons the instant composition and methods would have been obvious to one of ordinary skill in the art at the time of the instant invention.

2. Claims 1, 2, 5, 6, 12, 13, 18, 19, 20, 22, 25, 26, 37, 41, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mottahedeh (Canadian Patent

Application 2245254, Published 03/02/2000) in view of Davison et al. (US Patent 6638918 B2, Published 10/28/2003).

Applicant Claims

Applicant claims a pharmaceutical composition comprising: an ionogenic surfactant, a metal chelating complex, a solvent, and a pharmaceutically acceptable carrier. Applicant further claims a method of treating or preventing infection, dandruff, acne, and or dermatitis.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Mattahedeh are discussed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Mottahedeh lacks a teaching wherein the composition comprises an ionogenic surfactant and a metal chelating complex. This deficiency is cured by the teachings of Davison et al.

Davison et al. teach "The compositions provide hair care benefits when formulated into products such as shampoos ... especially anti-dandruff benefits ..." (See column 8, Lines 32-36). "There is provided an anti-dandruff composition comprising the chitosan composition and further anti-dandruff agent, especially zinc pyridinethione. Shampoos comprising the chitosan compositions of the invention may comprise the following ingredients: Deterative Surfactant The shampoo compositions for use herein contain from 8% to 40% by weight, of deterative surfactant, preferably from 10% to 30%,

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more preferably from 12% to 25%. Included among the deterative surfactant hereof is an anionic deterative surfactant component." (See column 8, Lines 59-67 and column 9, Lines 1-3). Additional components that can be added include in the composition includes micronutrients such as copper glycinate. (See column 27, Line 29).

***Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art to combine the teachings of Mottahedeh with Davison et al. One would have been motivated to do so because Mottahedeh teaches that the composition comprises shampoo components, including minerals and that the composition is useful in treating dandruff with a bactericide. Davison et al. teaches an antidandruff shampoo and therefore one would have expected success in combining the compositions of Mottahedeh and Brinkman et al. For the foregoing reasons the instant composition and methods would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ali Soroush
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